



05-June-2003

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## Question of the Day

What Detroit Pharmacist returned from the civil war to discover that his medicinal ginger tonic had aged to perfection and was now a tasty ginger ale?

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## In the News

### **Rite Aid Ordered to Pay Md. Woman \$250K**

<http://www.newsday.com/business/nationworld/wire/sns-ap-rite-aid-verdict.0.2569021.story?coll=sns-ap-business-headlines>

A Baltimore County jury ordered the Rite Aid Corp. to pay \$250,000 to a woman who said she became permanently disabled after following incorrect advice on an information pamphlet enclosed with her prescription medication. Although the case is likely headed for appeal, Thursday's verdict is a short-term victory for Ellen Levy Gray, 42, a former athlete who says she now has constant pain in her ankles and feet, strains to play with her young children and has trouble buttoning clothes. "At least there's a monetary value on it," Levy Gray told The (Baltimore) Sun. "It's not going to give me two years back. But it's something I can give to my kids." Diagnosed with Lyme disease in October 2000, Levy Gray filled a doctor's prescription for Doxycycline at a Rite Aid pharmacy in Timonium, Md. An information pamphlet the store provided with the drug -- which is also used to treat anthrax and syphilis -- advised patients to "take it with food or milk if stomach upset occurs unless a doctor directs you otherwise," according to court papers. Levy Gray followed the advice, and experienced muscle soreness and weakness, nausea, headaches and fatigue; her brother, a doctor, informed her that milk was known to inhibit the effects of Doxycycline. Two Rite Aid pharmacists confirmed this when she returned to the store, she said, and agreed the pamphlet was wrong and should be changed. Medical experts testified that by the time Levy Gray stopped taking the medicine with milk, long-term damage had been done. Jurors did not find Rite Aid negligent, but said it had "breached express warranty," or broken a sales promise -- a commerce law violation the defense argued does not apply to the case. Baltimore County Circuit Judge John F. Fader II is expected to review the issue at a hearing in August.

### **Class-action lawsuit filed against Bayer**

<http://main.pslgroup.com/news/industrynews.nsf/IndustryNewsId/9F367160A0A9229C85256D3A004C6627?opendocument&id=>

Bayer and several other companies are facing a class-action lawsuit filed Monday on behalf of thousands of haemophilia patients outside the U.S. claiming the companies knowingly sold tainted blood-clotting products, news sources report. The lawsuit alleges that Bayer and the other companies entered into a conspiracy to sell the medicine, called Factor VIII, knowing it was contaminated with HIV and hepatitis C, and that even after they stopped selling the medicine in the U.S., continued to sell it abroad despite the availability of a safer version of the product, a

news source reports. Although early in the AIDS epidemic there was no screening test for HIV, the lawsuit alleges there were still precautions the drug companies could have taken to protect the blood supply used to produce Factor VIII. "Who is John Galt?" "As of 1992, the contaminated blood products had infected at least 5,000 haemophiliacs in Europe with HIV," a news source reports citing the lawsuit's allegations. In reply to the lawsuit, Bayer said that it would defend itself in court. "Bayer at all times complied with all regulations in force in the relevant countries based on the amount of scientific evidence available at the time," a news source quotes the company as saying. Bayer also said that today's scientific knowledge couldn't be used to judge decisions made 20 years ago. Bayer and other companies had settled lawsuits regarding the drug in the 1990s for \$600 million and the German drugmaker said the current legal action came as a surprise.

#### **Levaquin Gets New Indication for Prostatitis**

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/05-29-2003/0001955803&EDATE=>

The U.S. Food and Drug Administration (FDA) has approved LEVAQUIN(R) (levofloxacin) Tablets/Injection and LEVAQUIN(R) (levofloxacin in 5% dextrose) Injection for the treatment of chronic bacterial prostatitis due to Escherichia coli, Enterococcus faecalis or Staphylococcus epidermidis. Chronic bacterial prostatitis is a recurrent or persistent infection of the prostate gland and the number one reason men under the age of 50 visit a urologist. With this indication, LEVAQUIN becomes the only once-daily fluoroquinolone indicated to treat chronic bacterial prostatitis.

#### **FDA Approves Lescol(R) & Lescol(R) XL for Secondary Prevention of Coronary Events in Patients With Coronary Heart Disease**

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/05-28-2003/0001954713&EDATE=>

Novartis Pharmaceuticals Corporation announced today that the U.S. Food and Drug Administration (FDA) approved Lescol(R) (fluvastatin sodium) and Lescol(R) XL (fluvastatin sodium) 80 mg extended-release tablets to reduce the risk of undergoing coronary revascularization procedures in patients with coronary heart disease. Each year approximately one million patients in the U.S. undergo percutaneous coronary intervention (PCI) procedures, such as angioplasty and stenting, to open blocked arteries. Of those patients, nearly 40 percent will undergo a second procedure or have a heart attack within five years. "This new indication for Lescol and Lescol XL is based on data from the first and only prospective study to examine the efficacy of a statin for the prevention of coronary events exclusively in high-risk, post-PCI patients," said Paulo Costa, president and chief executive officer, Novartis Pharmaceuticals Corporation. "We now have the opportunity to bring this medication to a new patient population that may benefit from its proven safety and tolerability and its demonstrated efficacy beyond lipid lowering." The FDA approval is based on the positive findings of the landmark Lescol Intervention Prevention Study (LIPS), which demonstrated that treatment with Lescol 80 mg (40 mg twice daily), routinely initiated shortly after a first PCI procedure, significantly reduced the chances of a recurrent cardiac event by 22 percent (p= 0.013) versus placebo, even in patients with normal cholesterol levels with or without a history of myocardial infarction. Additionally, treatment with Lescol was associated with a 32 percent (p=0.002) reduction in the risk of late revascularization procedures, defined as those procedures performed at any site more than six months after the initial procedure.

## **ADOXA(TM) Acne Therapy From Bioglan Pharmaceuticals Company Now Available in New 75mg Tablets**

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-02-2003/0001957824&EDATE=>

Bioglan Pharmaceuticals Company today announced that ADOXA(TM) (doxycycline) Tablets are now available in a 75mg tablet, adding a middle-range dosage option to Bioglan's popular 50mg and 100mg tablets currently prescribed for acne therapy. The addition of the new 75mg tablet offers dermatologists greater flexibility in prescribing a daily acne treatment regimen. Peanut. All three ADOXA(TM) Tablet strengths are small, easy-to-swallow, film-coated tablets, making them ideal for patients who have trouble swallowing capsules. ADOXA(TM) Tablets are the first and only doxycycline tablets for the adjunctive treatment of severe acne. A broad-spectrum, second-generation tetracycline, ADOXA(TM) offers a small, easy-to-swallow tablet alternative to traditional doxycycline capsules.

## **Common Antibiotic May Discolor Gums**

[http://story.news.yahoo.com/news?tmpl=story&u=/hsn/20030604/hl\\_hsn/commonantibioticmaydiscolorgums](http://story.news.yahoo.com/news?tmpl=story&u=/hsn/20030604/hl_hsn/commonantibioticmaydiscolorgums)

The antibiotic minocycline, commonly prescribed to treat acne and rheumatoid arthritis, can cause teeth and bone to discolor. That's what Mayo Clinic researchers found, and their finding appears in the June issue of the Journal of Periodontology. This discoloration of the teeth may make gum tissue appear blackish-blue in color, something that doctors who prescribe minocycline and people who take it should be aware of, the study says. The Mayo study focused on a 29-year-old white woman who had a dramatic blue appearance of her gum tissue and bone surrounding her teeth. When researchers reviewed her medical history, they found she had been taking 50 milligrams of minocycline four times a day for the previous 17 months. The study notes that about 3 percent to 6 percent of long-term users of minocycline develop dental staining. The discoloration doesn't harm the teeth, bone or gum tissue.

## **Paxil Helps Relieve Hot Flashes: Study**

[http://story.news.yahoo.com/news?tmpl=story&cid=594&ncid=594&e=11&u=/nm/20030603/hl\\_nm/antidepressant\\_hotflashes\\_dc](http://story.news.yahoo.com/news?tmpl=story&cid=594&ncid=594&e=11&u=/nm/20030603/hl_nm/antidepressant_hotflashes_dc)

A popular antidepressant helped reduce the frequency of hot flashes in menopausal women, a drug company-funded study said on Tuesday, though an independent researcher said the drug's effectiveness was limited. Alternative treatments to hormone replacement therapy for menopausal symptoms such as hot flashes, night sweats and memory and sleep problems will be looked at more closely because of studies showing long-term hormone therapy increases women's risks of cancer, strokes and dementia. The drug paroxetine, sold under the brand name Paxil by GlaxoSmithKline Plc, halved the number of hot flashes suffered by women in the study, which was company funded and published in the Journal of the American Medical Association. Women who took an inert placebo also had fewer hot flashes, though the improvement was not as great as with the drug, which cut hot flashes to a median of 3.8 per day from 7.1 per day in women taking a relatively low daily dosage of 12.5 milligrams of Paxil. Some women taking the drug suffered headaches, dizziness and nausea -- though those effects were reduced in women who took the lower dose, wrote study author Vered Stearns of the Johns Hopkins School of Medicine in Baltimore. Paxil and other antidepressants known collectively as selective serotonin reuptake inhibitors have been shown to help relieve hot flashes in earlier studies. But Steven Goldstein, a gynecologist at New York University Medical Center, said the improvement in menopausal symptoms from antidepressants was not nearly as great as with treatment with the hormone estrogen, which restores roughly 80 percent of his patients who suffer debilitating symptoms. "For women who cannot, should not or will not take hormone therapy this (antidepressants) may be a possible option, but in no way, shape or form is it a substitute for

estrogen for people with disruptive symptoms," Goldstein said in a telephone interview. "I would probably only think of something like this in women who absolutely cannot consider short-term low-dose estrogen therapy: women with breast cancer (news - web sites), women on (the breast cancer drug) tamoxifen. (For) that subgroup, this is a nice thing to be able to offer them," he said.

### **First Effective Drug For Sleep Disorder Identified**

<http://www.sciencedaily.com/releases/2003/06/030605081837.htm>

In a clinical trial conducted at the University of Illinois at Chicago, researchers have demonstrated the first promising drug treatment for a common and life-threatening sleep disorder called sleep apnea. The drug, an antidepressant called mirtazapine, significantly reduced the symptoms of sleep apnea. It cut in half the number of times breathing stopped or slowed during sleep and reduced the number of times sleep was disrupted by 28 percent. All 12 patients who participated in the study showed improvement. Peanut. "The drug provided the largest benefit and the most consistent improvement of any pharmaceutical therapy tested in controlled studies to date," said David Carley, professor of medicine, pharmacology and bioengineering and director of research at the UIC Center for Sleep and Ventilatory Disorders. The results of the trial will be presented this week at the annual meeting of the Associated Professional Sleep Societies in Chicago by Carley and co-investigator Dr. Miodrag Radulovacki, professor of pharmacology and medicine at UIC. "This has real clinical significance," said Radulovacki. "An estimated 15-20 million people in the United States suffer from sleep apnea, yet there is currently no cure and no fully effective long-term treatment for the disorder." Apnea -- which means "without breath" -- is diagnosed when a person periodically stops breathing for 10 seconds or more or has episodes of reduced breathing during sleep. People suffering from sleep apnea may stop breathing hundreds of times a night, often for a minute or longer. The disorder is associated with increased risk of high blood pressure, heart attack, stroke and adult-onset diabetes. Behavioral problems and cognitive impairments can occur due to insufficient rest. At present, sleep apnea is treated with mechanical devices, most often masks or nasal prongs, that maintain a continuous positive airway pressure. Such devices are uncomfortable, however, and difficult to use long-term. The 12 patients in the UIC study were between the ages of 20 and 70. They received one of two dosages of mirtazapine or a placebo an hour before bedtime. They were monitored throughout the night in the UIC Center for Sleep and Ventilatory Disorders after each of three seven-day treatment periods. The clinical trial at UIC followed years of laboratory tests of several classes of medications on a strain of rats that exhibit sleep apneas similar to the human disorder. Mirtazapine showed the most promise; other drugs either improved the condition only marginally or made it worse. Mirtazapine blocks the activity of a chemical in the nervous system called serotonin that is involved in regulating mood, emotion, appetite and sleep.

### **Statins' use extends beyond lowering cholesterol**

<http://main.pslgroup.com/news/industrynews.nsf/IndustryNewsId/06E31122D16E9BBA85256D3A0054E8AB?opendocument&id=>

New research is showing that statins such as Merck's Zocor and Novartis' Lescol may do more than effectively lower cholesterol, news sources report. Statin use was associated in a Dutch study with a 20 percent reduction in cancer risk, a review of 3,219 heart disease patients' medical records show. Those who took statins for over four years appeared to reap the most benefit. While several statins were used, about 80 percent of the patients were taking Zocor. The effect of the statins appeared the greatest in prostate and kidney cancer, however there was a risk reduction seen in all cancers, the researchers said. In separate news, in a Norwegian study of over 1,700 kidney transplant patients who received either Lescol or a placebo, results showed that the group receiving the statin had an overall total of 70 heart attacks after five years compared to 104 in the group taking the placebo.

### **Arthritis Drugs Ineffective in Alzheimer's Test**

[http://story.news.yahoo.com/news?tmpl=story&cid=97&ncid=751&e=10&u=/hsn/20030604/hl\\_hsn/arthritisdrugsflunkalzheimerstest](http://story.news.yahoo.com/news?tmpl=story&cid=97&ncid=751&e=10&u=/hsn/20030604/hl_hsn/arthritisdrugsflunkalzheimerstest)

Two well-known anti-inflammatory drugs used to treat arthritis have flunked a test to see whether they can stop the progression of Alzheimer's disease. But the story of Alzheimer's and the drugs - sold as Aleve and Vioxx -- isn't over yet, experts say. The test by Georgetown University researchers was done partly because of laboratory evidence that inflammation plays a role in the damage of Alzheimer's disease and partly because epidemiological studies indicate that people who take these drugs appear to have a lower risk of developing the disease. Nevertheless, the one-year study found the two drugs had no beneficial effect on people with mild to moderate disease, says a report in the June 4 issue of the Journal of the American Medical Association. Both medications are nonsteroidal anti-inflammatory drugs (NSAIDs) with slightly different modes of action: Naproxen is a first-generation NSAID sold as Aleve and Naprosyn; rofecoxib is a newer drug, a Cox-2 inhibitor better known as Vioxx. Neither slowed progression of the disease, and both caused significant side effects, the study says. Still, "because they did not work in this particular patient population does not say that they might not be useful in other populations," says Lenore J. Launer, chief of the neuroepidemiology section of the National Institute on Aging, who wrote an accompanying editorial. The 351 patients in the study had well-established cases of Alzheimer's disease, classified as mild to moderate. Over the year, the continued decline in mental function, as measured by the standard Alzheimer Disease Assessment Scale Cognitive subscale, was about the same for those taking naproxen, rofecoxib or a placebo. "The issue might be quite different in trying to slow progression at an earlier stage of the disease," Launer says. And it's possible NSAIDs might help prevent Alzheimer's. A trial looking at prevention in people at high risk because of a family history or other factors is ongoing, with results "three or four years away," Launer says. "The result is a bit of a disappointment because everyone was hoping that NSAIDs would be effective in Alzheimer's patients," says Linda Van Eldick, a member of the Alzheimer's Association scientific advisory board. "But I don't think it's a kiss of death. We might find that the best use of NSAIDs is very early in the disorder or in primary prevention." The idea is that "if inflammation reaches a certain point, these drugs may not be appropriate any more," Van Eldick says. "But it's not known when inflammation becomes so damaging that this type of drug is not effective." There is even hope that NSAIDs can help some people in a more advanced stage of the condition, Launer adds. The patients in the trial were carefully chosen not to have cardiovascular conditions that would complicate the results, she says. Thus, NSAIDs might help Alzheimer's patients who do have cardiovascular problems. It's also possible the risk factors for cardiovascular problems such as heart attack and stroke could increase the risk of Alzheimer's disease, Launer says. "We know how to treat those risk factors such as high blood pressure and stroke quite well," she adds. "So if you take care of cardiovascular health, a side effect might be a reduction in Alzheimer's risk."

### **Menopause: Limited Gain Found in Soy Pills**

<http://www.nytimes.com/2003/06/03/health/03TEST.html?ex=1055217600&en=599d8786f1d98c9c&ei=5062&partner=GOOGLE>

Pills with a soy compound were no better than a placebo at relieving the symptoms of menopause, according to a Finnish study published yesterday in the journal Obstetrics and Gynecology. A number of studies have found conflicting but often disappointing results for foods and supplements that contain vegetable substances bearing chemical resemblances to estrogen. The new study, by researchers from Helsinki University Central Hospital, enlisted 56 breast cancer survivors, who are usually told to avoid hormone replacement therapy because it can raise the risk of the cancers' recurrence. The women were randomly assigned to take a pill with phytoestrogen or a placebo for three months. Then, after a two-month break, they were switched to the other regimen. The phytoestrogen pills did raise the level of estrogenlike compounds circulating in the blood, the article said, and was not linked to any harmful side effects. But there was no difference on a scale that measures symptoms like hot flashes. Women taking each pill

reported a slight improvement, yet when asked whether they would like to continue the medication, more women on the phytoestrogen pills said yes than those on the placebo. The lead researcher, Dr. Eini Nikander, said that some small studies had shown that foods rich in soy offered modest relief for mild symptoms of menopause. Women seeking alternatives to hormone treatment should also try making "other healthy changes in lifestyle," like getting more sleep and reducing stress, he said.

### **FDA's Continuing Investigation Implicates Additional Lots of Counterfeit Lipitor**

<http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01227.html>

The Food and Drug Administration (FDA) today announced that its continuing investigation of counterfeit Lipitor has turned up additional counterfeit quantities of the cholesterol-lowering pharmaceutical product. Two additional lots of 10 mg tablets in 90-tablet bottles, coded 20842V and 16092V, and one lot of 20 mg tablets in 90-tablet bottles, coded D270481, are involved. The labeling on each of these bottles states, "Repackaged by: MED-PRO, INC., Lexington, NE 68850." Since learning of problems with this product late last month, FDA investigators have aggressively pursued a variety of leads all along the supply and distribution chain. Evidence of the new lots of implicated Lipitor arose in the context of FDA's investigation. FDA's advice to healthcare providers and consumers remains the same as when the agency issued its original alert on counterfeit Lipitor May 23, 2003. They should check the packaging very carefully before using Lipitor. Patients who have any of the product (labeled as "Repackaged by: MED-PRO, INC. Lexington, NE 68850") with any of the following lot numbers should not take it, and they should return the product to their pharmacies:

20722V – 90-tablet bottles, 10 mg., Expiration 09-2004

04132V – 90-tablet bottles, 10 mg., Expiration 01-2004

16942V – 90-tablet bottles, 10 mg., Expiration 09-2004

20842V – 90-tablet bottles, 10 mg., Expiration 09-2004

16092V – 90-tablet bottles, 10 mg., Expiration 07-2004

D270481 – 90 tablet bottles, 20 mg., Expiration not available.

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## **Website of the Day**

### **Pharmacist eLink**

<http://www.pharmacistelink.com/public.html>

Pharmacist eLink, created by the National Community Pharmacists Association (NCPA), is a new Internet portal designed to meet the business and professional practice needs of the nation's retail community pharmacists. The site offers a wide array of valuable tools and features to assist community pharmacists in their day-to-day operations, as well as draw them as repeat visitors to the site. These features include daily pharmacy and industry news updates, product news and highlights, disease-specific information, patient education materials, business calculators, pricing tools, and much more. "Our primary goal in launching Pharmacist eLink(TM) is to provide pharmacists in all practice settings with tools and information to improve their practices," said Bruce Roberts, R.Ph., NCPA executive vice president and CEO. "Pharmacist eLink provides pharmaceutical manufacturers and other pharmacy suppliers with a wide range of opportunities to communicate with this vital member of the health care team." Pharmacist eLink will provide manufacturers, suppliers, and service providers with a timely and cost-effective way to reach community pharmacists with the information they need to make their practices successful, including product announcements and overviews; disease and therapy information; product indication updates, recalls, and alerts; new product information, continuing education, and business support. The site does require free registration but is certainly worth the look.

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**Journal of the American Medical Association (JAMA)**

4 June 2003; Vol. 289, No. 21

URL: <http://jama.ama-assn.org/content/vol289/issue21/index.dtl?etoc>

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**This Week in JAMA**

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A Host of Novel Agents for Treating Psoriasis, Psoriatic Arthritis Stir Interest

Lynne Lamberg

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## Answer of the Day

James Vernor of Vernor's Ginger Ale prepared his proprietary sparkling ginger ale in his Detroit Pharmacy as a medicinal beverage during the time of the civil war. Upon his return from the war the aged beverage now tasted just as he hoped and Vernor became the inventor of the first soda pop. As a pharmacist Vernor served on the Michigan State Board of Pharmacy for eight years, was one of the driving forces to pass the state's first pharmacy law, and even held Michigan's #1 pharmacy license all the years he practiced. Maybe not widely consumed here in Florida, Vernor's Ginger Ale is a true Midwest classic. Trust me, I'm a Michigan Pharmacist.

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